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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KHARE, DEVESH	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 06/16/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,398	BALDRIDGE ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *20-24 and 45-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,25-44 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Election with *Traverse*

The response to restriction requirement received on 01/15/03 has been entered. Applicant's election with traverse of the method-of use claims defined by Group I (claims 1-44 and 61-63) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that "compositions and methods of use classified in the same class and subclass, would produce no burden on the Examiner". This is not found persuasive because the applicants' claims encompass the compositions of one or more compounds of formula I and to method of treating various diseases/conditions which would be burdensome to the examiner as it cannot be assumed that the method of treatment would be the same as the compositions of comprising one or more compounds of formula I. The requirement is still deemed proper and is therefore made FINAL.

Claims 45-60 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant has elected methods of treating bacterial infectious diseases in claims 1-22, 25-44 and 61-63.

Claims 20- 24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 1-19, 25-44 and 61-63 are currently pending in this application. An action on the merits of claims 1-19, 25-44 and 61-63 is contained herein below.

IDS

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate

paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

35 U.S.C. 112, first paragraph rejection

Claims 1-19, 25-44 and 61-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicant's specification fails to provide sufficient guidance or support to enable the worker of ordinary skill in the art a method for ameliorating or substantially preventing or for prophylactic treatment of a bacterial infectious disease, comprising contacting a subject with the cyclic aminoalkyl glucosaminide phosphate compounds of formula (I). The specification, while being enabling for the treatment of infection by a bacteria, does not reasonably provide enablement for the prevention of infection by a bacteria. Further, there is no enabling description of contacting a subject with the cyclic aminoalkyl glucosaminide phosphate compounds of formula (I), in claims 1-19, 25-44 and 61-63, for preventing a bacterial infectious disease. The worker of ordinary skill in the art would not be able to practice the instantly claimed method given the limited guidance provided by the disclosure herein provided. The mere statements that the compounds of the instant invention are likely to be effective, or expected to be effective

on the basis of very limited *in vitro* test data, are insufficient to enable the worker of ordinary skill in the art to practice invention. It is well known and established that the "law requires that disclosure in an application shall inform those skilled in the art how to use appellant's alleged discovery, not how to find out how to use it for themselves." *In re Gardner et al.,* 166 USPQ 138(CCPA 1970).

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

Claims 1-19, 25-44 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (WO 98/50399).

Claims 1-19, 25-44 and 61-63 are drawn to methods for ameliorating or substantially preventing a bacterial infectious disease with the cyclic aminoalkyl glucosaminide phosphate compounds (cyclic AGPs) of formula (I). The formula (I) is comprised of:

(1) a 2-deoxy-2-amino-ß-D-glucopyranose (glucosamine) having an azacycloalkyl or (azacycloalklyl)alkyl aglycon.

(2) compounds are phosphorylated at the 4 or 6 carbon on the glucosamine ring.

(3) normal fatty acid chains are attached to the 3'-stereogenic centers, the configuration of the 3'-stereogenic centers to which a normal fatty acyl chain, of length C6-C14, are attached, denoted "*1", "*2" and "*3", is R or S.

(4) the absolute stereochemistry of the carbon atoms between the cyclic aglycon unit and glucosamine unit can be R or S.

(5) the glycosidic atom "Y" can be in equatorial or axial position.

(6) the number of carbon atoms in the aglycon unit are represented by n,m,p and q, which are independently an integer from 0 to 6.

Additional claim limitations include the bacterial infectious disease is caused by a gram negative or a gram positive bacteria, pneumonia or nosocomial pneumonia, the infectious disease causing bacteria selected from the group consisting of Pseudomonas and administration to an animal.

Johnson et al. teach the use of cyclic AGP's compounds as adjuvants against bacterial pathogens (see page 1, lines 8-17 and page 2, lines 30-31). On page 3, lines 1-29 and page 4, lines 3-8, the cyclic AGP's compounds comprised of:

(1) a 2-deoxy-2-amino-ß-D-glucopyranose (glucosamine) having an aminoalkyl aglycon.

(2) compounds are phosphorylated at the 4 or 6 carbon on the glucosamine ring.

(3) normal fatty acid chains are attached to the 3'-stereogenic centers, the configuration of the 3'-stereogenic centers to which a normal fatty acyl chain, of length C7-C16, are attached, is R or S.

(4) the absolute stereochemistry of the carbon atoms between the aglycon unit and glucosamine unit can be R or S.

(5) the glycosidic atom "Y" can be in equatorial or axial position.

(6) the number of carbon atoms in the aglycon unit are represented by n,m,p and q, which are independently an integer from 0 to 6,

are disclosed. Also, the cyclic AGP compounds of the claims 62 and 63 are rendered obvious by the disclosure of these compounds. Johnson et al. also disclose on page 5, lines 6-8, the various ways to administer these compounds, which are rendered obvious by the disclosure

Johnson et al. differ from the applicant's invention that Johnson et al. do not provide an explicit example of a cyclic AGP where the glucosamine unit is attached to an aglycon cyclic in structure, however Johnson et al. do provide motivation to use various types of cyclic AGP's to treat bacterial infectious diseases such as pneumonia (see Example 3 on page 85). It is noted that Johnson et al. does not provide specific disclosure regarding a gram negative or gram-positive bacteria and a species of bacteria such as Pseudomonas.

Therefore, one of ordinary skill in the art would have found the applicants methods for ameliorating or substantially preventing a bacterial infectious disease with the cyclic aminoalkyl glucosaminide phosphate compounds (cyclic AGPs), to have been obvious at the time the invention was made having the above reference before him because Johnson et al. teach the use of cyclic AGP's compounds as adjuvants against bacterial pathogens and use these compounds to treat pneumonia. A skilled artisan would be motivated to make routine modifications to produce a cyclic AGP's compounds for pharmaceutical delivery.

State of the Art References

The following references further reflect the current state of the art:

Taniguchi et al. (U.S. Patent 6,531,453) –discloses the therapeutic agents containing glycosylceramides.

Behar et al. (U.S. Patent Pub. 2002/ 0115624) – discloses glycosylceramides for treating bacterial and fungal infections.

Hersch et al. (U.S. Patent 6,221,388) –discloses a liposomal amino glycoside formulation to treat the bacterial infections.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (703)605-1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
April 2,2003

SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1600